

DEC - 2 2003

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Endoscopy Division

Smith & Nephew, Inc.
150 Minuteman Road, Andover, MA 01810-1031 U.S.A.
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Smith+Nephew

510(k) Summary

Smith & Nephew IUR Morcellation System

Date Prepared: June 9, 2003

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter's Name

Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist II
Phone: (978) 749-1494
Fax: (978) 749-1443

C. Device Name

Trade Name:	Smith & Nephew IUR Morcellation System
Common Name:	Mechanical Tissue Resection System
Classification Name:	Hysteroscopes and Accessories

D. Predicate Devices

The Smith & Nephew IUR Morcellation System is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution: FemRx™ Focused Monopolar (FMP) ^{opera} Star System, K964441. The materials of construction and design are similar to the following legally marketed devices in commercial distribution: Dyonics Disposable Arthroscopic Blades, K953695 and Smith & Nephew Dyonics Power Control Unit, K954989

E. Description of Device

The Smith & Nephew IUR Morcellation System is used to perform hysteroscopic surgery for the removal of submucous myomas and endometrial polyps. This system incorporates the use of an operative channel hysteroscope, a disposable shaver morcellator, a motor drive unit, and a motor drive control unit. Smith &

Nephew's IUR Morcellation System uses mechanical resection to remove endometrial polyps and submucous myomas. The Smith & Nephew IUR Morcellation control unit meets UL 2601-1 and IEC 60601-1, electrical safety standards for BF type equipment.

D. Intended Use

The Smith & Nephew IUR Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

E. Comparison of Technological Characteristics

The Smith & Nephew IUR Morcellation System is substantially equivalent in design, materials of construction, function and/or intended use to the following devices cleared for commercial distribution:

FemRx™ Focused Monopolar (FMP) ^{opera} Star System, K964441

Smith & Nephew Dyonics Disposable Arthroscopic Blades, K953695

Smith & Nephew Dyonics Power Control Unit, K954989



Janice Haselton

Regulatory Affairs Specialist II



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 2003

Ms. Janice Haselton
Regulatory Affairs Specialist
Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
ANDOVER MA 01810

Re: K031787
Trade/Device Name: The Smith & Nephew IUR
Morcellation System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: September 24, 2003
Received: September 25, 2003

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031787

Device Name: __ The Smith & Nephew IUR Morcellation System

Indications For Use:

The Smith & Nephew IUR Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Johnson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031787